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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/361,630 07/27/99 ZUKER

C 2307E-084210

020350 HM22/1107
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EXAMINER

WINKLER, U

ART UNIT

PAPER NUMBER

1648

DATE MAILED:

11/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/361,630

Applicant(s)

ZUKER ET AL.

Examiner

Ulrike Winkler, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-93 is/are pending in the application.
- 4a) Of the above claim(s) 1-31, 41-45 and 48-93 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-40, 46 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 and 6 20) ☐ Other: _____

DETAILED ACTION

Applicant's election with traverse of Group I with species election TCP 2 in Paper No. 10 is acknowledged. The traversal is on the grounds that the groups stem from a common concept and theory and therefore would not place a substantial burden on the examiner. This is not found persuasive because the groups are classified in different classes and subclasses, therefore, the searches would not be coextensive and would be an undue burden to search. Claims 32-40, 46 and 47 are under consideration in the instant office action.

The requirement is still deemed proper and is therefore made FINAL.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1648**.

Specification

The disclosure is objected to because of the following informalities:

There appears to be a typographical error on page 4, line 1, which reads: the taste cell polypeptides are designated as TCP1, TCP3 and TCP3, it would appear that they should read TCP1, TCP2 and TCP3. Appropriate correction is required.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper No. 3 and 6, are attached to the instant Office action.

Claim Rejections - 35 USC § 101, Claim Rejections - 35 USC § 112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-40, 46 and 47 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The instant invention is drawn to polynucleotides that encodes the polypeptides of SEQ ID NO: 3 and 4 which are associated with taste receptor cells. The claimed polynucleotides are not supported by a specific and substantial utility or a well established utility because the specification states only that the polynucleotides and the corresponding polypeptides are members of the taste transduction pathway and represent receptors, ion channels and signaling molecules involved in taste transduction. Further experimentation is necessary to attribute a utility to the claimed polynucleotides (*Brenner v Manson* 148 USPQ 689, 1966). Note, because the claimed invention is not supported by a specific and substantial utility asserted utility for the reasons set forth above, credibility has not been assessed.

Claims 32-40, 46 and 47 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above. The specification associated SEQ ID NO: 3 and 4 with expression in taste cells and the taste transduction pathway, but does

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not correlate the sequences with a specific function. Therefore, one of ordinary skill in the art would not know how to use the claimed invention.

Claims 32-40, 46 and 47 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification discloses SEQ ID NO:3 and 4, but does not reasonably provide enablement for the other homologous sequences or polynucleotide sequences comprising the SEQ ID NO: 3 and 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate with scope of these claims. Therefore, it would be unpredictable which polynucleotide sequences with 70% identity would provide the critical structural and functional properties, as it relates to the nucleic acids as claimed.

The specification does not provide sufficient guidance and direction as to the nature and identification of these nucleic acids, including those that have 70% sequence identity at the amino acid level. It well known in the art at the time the invention was made that the amino acid sequence of a protein determines the structural and functional properties. Predictability of which changes can be tolerated in a proteins amino acid sequence and still retain similar activity requires a knowledge of, and guidance with regard to, which amino acids in the protein's sequence are tolerant of modifications and which are conserved (i.e. expectedly intolerant to modifications). Detailed knowledge of the ways in which the proteins structure relates to the function is also necessary. The specification merely discloses the polynucleotide sequences

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encoding the polypeptides of SEQ ID NO: 3 and 4. It would be undue burden for one of skill in the art to practice the claimed invention in terms of making all the homologous sequences from the disclosed sequences, because the specification provides no guidance as to the many different homologous sequences that can be produced. A 70% homology of SEQ ID NO: 3 and 4 on the amino acid level can corresponds to a nucleotide difference 220-658 nucleotides. These nucleotide substitutions can be arranged contiguously or sparsely at different positions on a sequence. The state of the art is such that one can not predict what substitution will result in significant structural or functional changes. The classic example of structural/functional differences is hemoglobin where a single amino acid substitution due to a single nucleotide change has significant consequences on the ability of the mutant hemoglobin to carry oxygen. A second example comes from a bacterial protease (Riffkin et al. Gene 1995): here a change in two nucleotides of the protease sequence results in the difference between virulent and benign infection. This small difference does not only results in epitope differences but also results in changes to the thermostability, elastolytic and caseinolytic activity of the protease. There is no guidance in the specification to teach where the instant sequences should be substituted, and therefore, the functionality of the protein would be unpredictable. Moreover, one of skill in the art would not know which substitutions would retain the characteristics of SEQ ID NO: 3 and 4 without undergoing undo experimentation. Therefore, the instant invention is not enabled.

Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe an isolated nucleic acid from human that

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corresponds to SEQ ID 3 or 4. Therefore, there is lack of written description for the isolated human nucleic acid.

Conclusion

No claims are allowed.

SEQ ID 3, 4, 13, 13, 21 and 22 are apparently free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.



JEFFREY STUCKER
PRIMARY EXAMINER